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One Medrad Drive			DELLA, JAYMI E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.	Applicant(s)			
10/599,366	UBER ET AL.			
Examiner	Art Unit			
JAYMI DELLA	3739			

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,

- WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
- after SIX (6) MONTHS from the mailing date of this communication.

 If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
 Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
 - earned patent term adjustment. See 37 CFR 1.704(b).

a) The energification is objected to by the Evaminer

a) All b) Some * c) None of:

Status	
1)🛛	Responsive to communication(s) filed on 11 February 2011.
2a)🛛	This action is FINAL . 2b) This action is non-final.
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)⊠	Claim(s) 1-37,39-51 and 53-56 is/are pending in the application.
	4a) Of the above claim(s) 1-17,21-29 and 45-50 is/are withdrawn from consideration.
5)	Claim(s) is/are allowed.
6)🛛	Claim(s) 18-20, 30-37, 39-44, 51, and 53-56 is/are rejected.
7)	Claim(s) is/are objected to.
8)	Claim(s) are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

1.∐	Certified copies of the priority documents have been received.
2.	Certified copies of the priority documents have been received in Application No
3.	Copies of the certified copies of the priority documents have been received in this National Stage
	application from the International Bureau (PCT Bule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

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Paper No(s)/Mail Date	6) Other:	
Information Disclosure Statement(s) (PTO/SB/08)	Notice of Informal Patent Application	
Notice of Draftsperson's Patent Drawing Review (PTO-946)	Paper No(s)/Mall Date	-
1) M Notice of References Cited (P10-892)	4) Interview Summary (PTO-413)	

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DETAILED ACTION

The following is a Final Office Action on the merits. Claims 18-20, 30-37, 39-44,
 and 53-56 are addressed below.

Response to Amendment

 Acknowledgment is made to the amendment received 2/11/2011, amending claims 18, 30, 34, 51, and 55. Claims 38 and 52 are cancelled and claims 1-17, 21-29, and 45-50 are withdrawn.

Claim Objections

 Claim 30 is objected to because of the following informalities: claim recites "both either". It is suggested to delete "either" as other amended claims recites only "both".
 Appropriate correction is required.

Claim Rejections - 35 USC § 112

- 4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms Concerning enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 5. Claims 18-20, 30-37, 40-44, 51, and 53-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way

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Concerning reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- 6. Amended claims 18, 30, 34, and 51 all recite the limitation of "a penetator ...being energized with mechanical energy via an actuator...said means comprising at least two effectors that are operatively connected to the actuator" or "at least one component...energized with mechanical energy via an actuator...said means comprising at least two effectors that are operatively connected to the actuator". From Fig. 1, it appears that the "penetrator" and the "effectors" are the same element. Further the effectors illustrated in Fig. 2a-13b illustrated penetrating effectors. For the purposes of examination, the claims will be interpreted as follows: --said means comprising at least two penetrators that are operatively connected to the actuator—(claim 31, 30); --said means comprising at least two penetrating members that are operatively connected to the actuator—(claim 34); --said means comprising at least two penetrating members that are operatively connected to the actuator—(claim 51).
- The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 18-20, 30-37, 40-44, 51, and 53-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. Amended claims 18, 30, 34, and 51 all recite the limitation of "a penetator ...being energized with mechanical energy via an actuator...said means comprising at least two effectors that are operatively connected to the actuator" or "at least one

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component...energized with mechanical energy via an actuator...said means comprising at least two effectors that are operatively connected to the actuator". From Fig. 1, it appears that the "penetrator" and the "effectors" are the same element. Further the effectors illustrated in Fig. 2a-13b illustrated penetrating effectors. For the purposes of examination, the claims will be interpreted as follows: --said means comprising at least two penetrators that are operatively connected to the actuator—(claims 18, 30); -- said means comprising at least two penetrating members that are operatively connected to the actuator—(claim 34); --said means comprising at least two penetrating members that are operatively connected to the actuator—(claim 51).

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- Claim 30 recites the limitation "the conduit insertion device" in II. 2-3 and 4-5.
 There is insufficient antecedent basis for this limitation in the claim.
- 11. Claim 34 recites "a tissue resident conduit", "at least one component that is energized with mechanical energy", and "said actuator having means to energize the tissue resident conduit". It is unclear if the "at least one component" is the same as "the tissue resident conduit" since both are being energized with energy by the actuator. The claim will be interpreted where the at least one component is the penetrator/effector, since the specification discloses the "tissue resident conduit" as a catheter with blunt edges that does not penetrate, cut or damage tissue through which a penetrator/component is place through and energized ([0031-0032]).

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Claim Rejections - 35 USC § 103

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

- 13. Claims 18-20, 30-36, 42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giba et al. (5,876,373, previously cited) in view of Neuenfeldt (2002/0143269) and Balbierz et al. (2002/0026188).
- 14. Concerning claim 18, as illustrated in Fig. 9A-B, Giba discloses a device for penetrating tissue and positioning a catheter, comprising: a catheter (catheter 100) comprising a passage therethrough; and a penetrator (piercing tube 214) in operative connection with the catheter, the penetrator being energized with mechanical energy via an actuator (spring 208; Col. 11, II. 29-45) in a repetitive manner to assist in penetrating tissue (applying pressure to plate 200 repeatedly; Col. 11, II. 29-45), said actuator (208) having means to energize the penetrator in an axial direction (Fig. 9A-B)

Giba fails to disclose the means energizing the penetrator in a rotational direction. However, Neuenfeldt discloses a needle that is inserted with an actuator (2) that imparts mechanical energy to rotate the needle while its being inserted into tissue. At the time of the invention, it would have been obvious to one of ordinary skill in the art to also penetrate using rotational motion in order to provide the benefit of lowering the insertion force as taught by Neuenfeldt. ([0033]; Fig. 1-2)

Giba et al. fail to disclose the device comprising at least two penetrators operatively connected to the actuator. However, Balbierz et al. disclose a device for

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penetrating tissue with varying embodiments that have one or more effectors (18) mechanically actuated by advancement device/member (15,34) through catheter (12). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- Concerning claim 19, Giba discloses the penetrator is removably positioned within the passage of the catheter (e.g. by removing threadable end cap 202) (Col. 11, II. 12-14).
- Concerning claim 20, Giba discloses the penetrator is positioned on the exterior of the catheter when extended (Fig. 9B).
- 17. Concerning claim 30, as illustrated in Fig. 9A-B, Giba discloses a method of inserting a tissue resident conduit (catheter 100) into tissue, comprising the step: energizing at least a portion of a forward end of the tissue resident conduit (piercing tube 214) with mechanical energy via an actuator to assist in penetrating tissue (spring 208; Col. 11, II. 29-45), said actuator (208) having means to energize the penetrator in an axial direction (Fig. 9A-B).

Giba fails to disclose the means energizing the penetrator in a rotational direction. However, Neuenfeldt discloses a needle that is inserted with an actuator (2) that imparts mechanical energy to rotate the needle while its being inserted into tissue. At the time of the invention, it would have been obvious to one of ordinary skill in the art

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to also penetrate using rotational motion in order to provide the benefit of lowering the insertion force as taught by Neuenfeldt. ([0033]; Fig. 1-2)

Giba et al. fail to disclose the device comprising at least two penetrators operatively connected to the actuator. However, Balbierz et al. disclose a device for penetrating tissue with varying embodiments that have one or more effectors (18) mechanically actuated by advancement device/member (15,34) through catheter (12). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- Concerning claim 31, Giba discloses the tissue resident conduit is a catheter (Col. 11, II. 29-45).
- Concerning claim 32, Giba discloses the tissue resident conduit is deflectable/flexible (Abstract).
- Concerning claim 33, Giba discloses the tissue resident conduit has a blunt forward surface (118) (Fig. 9A).
- 21. Concerning claim 34, as illustrated in Fig. 9A-B, Giba discloses a device for inserting a tissue resident conduit (catheter 100) comprising: at least one component (piercing tube 214) that is energized with mechanical energy via an actuator (spring 208; Col. 11, II. 29-45) during penetration to assist in penetrating

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tissue, said actuator having means to energize the at least one component in an axial direction (applying pressure to plate 200 repeatedly; Col. 11, II, 29-45).

Giba fails to disclose the means energizing the component in a rotational direction. However, Neuenfeldt discloses a needle that is inserted with an actuator (2) that imparts mechanical energy to rotate the needle while its being inserted into tissue. At the time of the invention, it would have been obvious to one of ordinary skill in the art to also penetrate using rotational motion in order to provide the benefit of lowering the insertion force as taught by Neuenfeldt. ([0033]; Fig. 1-2)

Giba et al. fail to disclose the device comprising at least two components operatively connected to the actuator. However, Balbierz et al. disclose a device for penetrating tissue with varying embodiments that have one or more components (18) mechanically actuated by advancement device/member (15,34) through catheter (12). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- 22. Claim 35 is rejected upon the same rationale as presented for claims 30 and 32.
- Concerning claim 36, Giba discloses a mechanism (steering) capable of directing the penetration of the tissue resident conduit (Col. 8, II.13-18).
- 24. Claim 42 is rejected upon the same rationale as presented for claim 31.

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 Concerning claim 44, Giba discloses a component (214) capable of penetrating through a blood vessel wall when enough force is presented.

- Claims 30-37 and 39-44 are rejected under 35 U.S.C. 103(a) Cosman et al. (6.478,793, previously cited) in view of Balbierz et al. (2002/0026188).
- 27. Concerning claim 30, as illustrated in Fig. 9A-B, Giba discloses a method of inserting a tissue resident conduit into tissue (cannula 142; Col. 7, II. 28-36), comprising energizing at least a portion of a forward end of a conduit insertion device with mechanical energy via an actuator to assist in penetrating tissue (external driver 180/124 energizes drill stylet 160 or electrode shaft 80, 84 with mechanical energy to penetrate tissue; Col. 7, II. 11-58, said actuator (180/124) having means to energize the forward end of the conduit insertion device in both an axial and rotational direction (external driver pushes and turns shaft during penetration of tissue and bone; Col. 7, II. 20-25).

Cosman fails to disclose the device comprising at least two conduit insertion devices operatively connected to the actuator. However, Balbierz et al. disclose a device for inserting a tissue resident conduit (12) with varying embodiments that have one or more tissue penetrating components (18) mechanically actuated by advancement device/member (15,34,24) (Fig. 18A-19). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of

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the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- Concerning claim 31, Cosman discloses the tissue resident conduit to be a catheter (Fig. 3).
- 29. Concerning **claim 32**, Cosman discloses the tissue resident conduit (142) to be flexible (Col. 7, II. 61-62).
- 30. Concerning **claim 33**, Cosman discloses the tissue resident conduit (142) to have a blunt forward surface (Fig. 3).
- 31. Concerning claim 34, as illustrated in Fig. 3 and 5, Cosman discloses a device for inserting a tissue resident conduit (cannula 142; Col. 7, II. 28-36) comprising: at least one component (drill stylet tip 164 or alternative embodiment electrode shaft tip 94; Col. 7, II. 11-58, Fig. 2) that is energized with mechanical energy via an actuator (external driver 180/124 energizes components 164/94; Col. 7, II. 21-25 and 42-49) during penetration to assist in penetrating tissue, said actuator having means to energize the at least one component in both an axial and rotational direction (external driver pushes and turns shaft during penetration of tissue and bone; Col. 7, II. 20-25).

Cosman fails to disclose the device comprising at least two components operatively connected to the actuator. However, Balbierz et al. disclose a device for inserting a tissue resident conduit (12) with varying embodiments that have one or more tissue penetrating components (18) mechanically actuated by advancement device/member (15.34.24) (Fig. 18A-19). At the time of the invention, it would have

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been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co.. 193 USPQ 8.

- 32. Concerning **claim 35**, Cosman discloses the tissue resident conduit (142) to be flexible and the energized component (160/84) to be position on a forward end of the tissue resident conduit (142) ((Col. 7, II. 61-62; Fig. 3).
- Concerning claim 36, Cosman discloses a mechanism (driver 180/124) for directing penetration of the tissue resident conduit (142) (Col. 7, II. 28-49).
- 34. Concerning claim 37, Cosman discloses a rigid penetrator (160/80, 84) with the energized component (164/94) positioned on the forward end of the penetrator (160/80, 84), the tissue resident conduit (142) being in operative and removable connection with the penetrator (160/80, 84) so that the penetrator (160/80, 84) can be removed from penetrated tissue while the tissue resident conduit (124) remains (Col. 7, II. 12, 36-38, and 47-53).
- 35. Concerning claims 39-40, Cosman discloses the penetrator (160/80, 84) is positioned within and adjacent the conduit (142) during penetration (Col. 7, II. 42-49; arrows of Fig. 3).
- 36. Claim 41 is rejected upon the same rationale as presented for claim 32.
- 37. Claims 42-43 are rejected upon the same rationale as presented for claim 31.

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 Concerning claim 44, Cosman discloses an effector 184 that is capable of penetrating through a wall of a blood vessel (Col. 7, Il. 53-56).

- Claims 51 and 53 are rejected under 35 U.S.C. 103(a) in view of Saadat et al. (6,120,520, previously cited) in view of Neuenfeldt (2002/0143269) and Balbierz et al. (2002/0026188).
- 40. Concerning claims 51 and 53, as illustrated in Fig. 5-6 and 8, Saadat discloses a non-coring needle comprising a penetrating member (non-coring tissue piercing cone 61; Col. 6, II. 2-3) that is energized with mechanical energy via an actuator (drive shaft 62 is coupled to piston 64 and is disposed for reciprocation response to movement of piston 64 or alternative embodiment of mechanical drive system; Col. 6, II. 2-6 or Col. 8, II. 6-18), a forward end of the penetrating member comprising a forward extending section comprising at least two points spaced from each other and being adapted to pierce tissue (any two points on forward end of cone 61 are adapted to pierce tissue) said actuator having means to energize the penetrating member in an axial direction (drive shaft 62 is coupled to piston 64 and is disposed for reciprocation response to movement of piston 64 or alternative embodiment of mechanical drive system; Col. 6, II. 2-6 or Col. 8, II. 6-18).

Saadat fails to disclose the means energizing the penetrating member in a rotational direction. However, Neuenfeldt discloses a needle that is inserted with an actuator (2) that imparts mechanical energy to rotate the needle while it's being inserted into tissue. At the time of the invention, it would have been obvious to one of ordinary

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skill in the art to also penetrate using rotational motion in order to provide the benefit of lowering the insertion force as taught by Neuenfeldt. (100331: Fig. 1-2)

Saadat fails to disclose the device comprising at least two penetrating members operatively connected to the actuator. However, Balbierz et al. disclose a device for inserting a tissue resident conduit (12) with varying embodiments that have one or more tissue penetrating components (18) mechanically actuated by advancement device/member (15,34,24) (Fig. 18A-19). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

- 41. Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saadat et al. (6,120,520, previously cited) in view of Neuenfeldt (2002/0143269) and Balbierz et al. (2002/0026188), as applied to claim 51, in further view of Ross et al. (6,702,790, previously cited).
- 42. Concerning claim 54, Saadat as modified by Neuenfeldt and Balbierz et al. fail to disclose the two points positioned to stabilize tissue for penetration. However, Ross et al. discloses a needle (20) with two points (22) positioned to stabilize tissue for penetration (Col. 3, II. 29-31; Fig. 4). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have a needle with two points positioned to

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stabilize tissue for penetration to provide the benefit of enhancing penetration as taught by Ross et al. (Col. 2. II. 12-17).

- 43. Claims 55-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unsworth (6,520,927, previously cited) in view of Balbierz et al. (2002/0026188).
- 44. Concerning claim 55, as illustrated in Fig. 1-2, Unsworth discloses a blunt needle comprising an effector that does not readily penetrate tissue (needle 4 can have a blunt effector end; Col. 6, II. 57-59) and is operatively connected to at least one actuator (linear screw drive 3; Col. 6, II. 41) that when energized with mechanical energy enables the needle to readily penetrate tissue, said actuator having means to energize the needle in both an axial and rotational direction (linear screw drive 3 moves needle 4 back and forth in an axial and rotational direction to penetrate tissue; Col. 6, II. 36-41Col. 7-8, II. 50-3).

Unsworth fails to disclose the device comprising at least effectors operatively connected to the actuator. However, Balbierz et al. disclose a device for inserting a tissue resident conduit (12) with varying embodiments that have one or more tissue penetrating components (18) mechanically actuated by advancement device/member (15,34,24) (Fig. 18A-19). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have more than one penetrator in order to provide the benefit of penetrating more than one are of tissue at a time to provide a quicker procedure and since it has been held that mere duplication of the essential working

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parts of a device involves only routine skill in the art. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

The Examiner notes to Applicant: "rotation" is defined as: the act of rotating; a turning around as on an axis (www.dictionary.com). Further, the claim does not recite that the "rotational direction" means rotation about the needles longitudinal axis, and that rotation can be taking place around any axis.

45. Concerning **claim 56**, Unsworth discloses a conduit within hollow needle (4) such that fluid can be delivered to the tissue or material removed from the tissue since the needle is hollow (Col. 6, Il. 54-55).

Response to Arguments

46. Applicant's arguments with respect to claims 18-20, 30-37, 39-44, 51, and 53-56 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/ Supervisory Patent Examiner, Art Unit 3739

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/J. D./ Examiner, Art Unit 3739 April 5, 2011